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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte LIONEL BRETON, ISABELLE BUREAU-FRANZ,
and
CHANTAL FANCHON,
Appellants¹

Appeal 2010-000353
Application 10/505,305
Technology Center 1600

Before ERIC GRIMES, CAROL A. SPIEGEL, and
MELANIE L. MCCOLLUM, *Administrative Patent Judges*.

SPIEGEL, *Administrative Patent Judge*.

DECISION ON APPEAL²

¹ The real party in interest is NESTEC S.A. (Appellants' Appeal Brief filed 3 March 2009 ("App. Br.") at 2). This decision also cites to the Examiner's Answer mailed 28 May 2009 ("Ans."), Appellants' Reply Brief filed 23 July 2009 ("Reply Br."), and the Specification of the '305 Application ("Spec.").

² The two-month period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

Appellants appeal under 35 U.S.C. § 134(a) from an Examiner's final rejection of claims 1-10 and 25-30. Claims 11-24, the only other pending claims, stand withdrawn from consideration as directed to a non-elected invention. (App. Br. 4; Ans. 2.) We have jurisdiction under 35 U.S.C. § 134. We AFFIRM.

I. Statement of the Case

The subject matter on appeal is directed to an orally administrable composition containing a photoprotecting effective amount of at least one probiotic lactic acid bacterium, from 10^{-12} to 20 % by weight of at least one carotenoid, a yeast extract, and an orally acceptable carrier.

According to the '305 Specification, "photoprotection" describes an "attempt to block or reduce the adverse clinical, histological and immunological effects of solar radiation exposure on the skin" (Spec. 3:14-16), such as erythema, inflammation, sun burn, barrier function, photoageing, and alteration of the immune system (*id.* at 2:24-29).

According to the '305 Specification, the probiotic lactic acid bacteria is present in an amount of at least 10^5 cfu/g carrier, preferably from about 10^5 to 10^{15} cfu/g carrier (*id.* at 5:11-15).

Claim 1 is illustrative and reads (App. Br. i):

1. An orally administrable composition for the photoprotection of the skin comprising a photoprotecting effective amount of at least one probiotic lactic acid bacterium, and at least one carotenoid, wherein the at least one carotenoid is present in the composition in an amount from 10^{-12} % to 20% by weight, included in an orally acceptable carrier, the composition further comprising a yeast extract.

The probiotic lactic acid bacterium of claim 1 may be selected from Lactobacilli and Bifidiobacteria (claim 2), e.g., *Lactobacillus johnsonii* (CNCM I-1225), *Lactobacillus paracasei* (CNCM I-2116), *Bifidobacterium adolescentis* (CNCM I-2168), or *Bifidobacterium longum* (CNCM I-2170) (claim 4). The carotenoid of claim 1 may be α -carotene, β -carotene, γ -carotene, lycopene, zeaxanthine, and/or luteine (claim 26). The carrier of claim 1 may be a food (claim 7), a drinkable solution (claim 9), a pharmaceutical carrier (claim 27), or an oral nutritional supplement (claim 29).

The Examiner rejected claims 1-10 and 25-30 as unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Cavaliere Vesely,³ Runge,⁴ Berggren,⁵ Brassart,⁶ and Reddy⁷ (Ans. 3-5).⁸

The Examiner found that Cavaliere Vesely, Runge, and Berggren teach an orally administrable composition comprising at least one probiotic

³ European Patent Application EP 1 020 123 A1, *Beverages containing live lactic bacteria*, published 19 July 2000, by Cavaliere Vesely et al. ("Cavaliere Vesely").

⁴ US Patent 7,037,708 B1, *Dried Microorganism Cultures and Method for Producing Same*, issued 2 May 2006, to Runge et al., based on application 09/673,136, filed 29 April 1999 ("Runge").

⁵ International Patent Publication WO 00/70972 A1, *New Composition*, published 30 November 2000, by Berggren et al. ("Berggren").

⁶ US Patent 5,603,930, *Lactobacillus Johnsonii CNCM I-1225*, issued 18 February 1997, to Brassart et al. ("Brassart").

⁷ US Patent 4,806,368, *Shelf Life and Subsequent Growth of Lactobacillus Acidophilus, Propionibacterium Shermanii and Leuconostoc Citrovorum in Dietary Fiber Based Supplement Preparation*, issued 21 February 1989, to Malireddy S. Reddy ("Reddy").

⁸ The Examiner withdrew US Patent 6,156,355, issued to Shields, Jr. et al., from the final rejection because she deemed it a duplicative reference (see the Office communication mailed 9 October 2009).

lactic acid bacterium, a carotenoid, and an ingestible carrier (*id.* at 3). The Examiner found that Brassart teaches that *Lactobacillus johnsonii* CNCM I-1225 is a known, orally administrable probiotic lactic acid bacterium (*id.* at 4). The Examiner found that Reddy teaches that adding yeast extract to *Lactobacillus* compositions is known for its viability enhancement and provision of vitamin B (*id.* at 6). The Examiner found that the concentrations of components discussed in the references appear to be substantially the same as claimed (*id.* at 4). If not, the Examiner concluded that the claimed concentrations would have been a matter of routine optimization of results effective variables (*id.*). The Examiner further concluded that it would have been obvious to modify the compositions of Cavaliere Vesely, Runge, and Berggren by including known probiotic strains, e.g., *Lactobacillus johnsonii* CNCM I-1225, as taught by Brassart, and yeast extract, as taught by Reddy, to provide "a healthful composition comprising a probiotic strain in a photoprotecting amount known to have favorable effects against disease and ... carotenoids such as β -carotene as well as yeast extract, materials known to have at least antioxidant effects and containing vitamin B, respectively" (*id.* at 4-5).

Appellants argue that (1) the cited references, alone or in combination, fail to teach or suggest all elements of the claimed invention, and that (2) a skilled artisan would have had no reason to combine the cited references, none of which are directed to skin photoprotection, (3) absent hindsight reconstruction (App. Br. 9-16; Reply Br. 2). Appellants further argue that the provided Affidavit⁹ demonstrates that the claimed composition provides

⁹ Affidavit Under 37 C.F.R. § 1.132 by Isabelle Bureau-Franz, dated 8 April 2008, with attached Exhibit B ("Affidavit").

unexpected synergistic photoprotective effects (App. Br. 11-15; Reply Br. 2-5).

Appellants have not separately argued the patentability of any of the dependent claims on appeal (see e.g., App. Br. 10-11). Therefore, we decide this appeal on the basis of claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

At issue is whether the evidence of record supports a *prima facie* conclusion that it would have been obvious to modify the compositions of Cavaliere Vesely, Runge, and Berggren by adding a yeast extract thereto; and, if so, whether Appellants have provided evidence that, when weighed with the evidence of obviousness, is sufficient to overcome the *prima facie* conclusion of obviousness.

II. Findings of Fact

The following findings of fact ("FF") are supported by a preponderance of the evidence of record.

A. Cavaliere Vesely

- [1] Cavaliere Vesely discloses non-milk beverages containing probiotic lactic acid bacteria (Cavaliere Vesely ¶¶ 1, 8, 10, 21, 26, 45).
- [2] The probiotic bacteria provide a number of beneficial effects, including stimulating the immune system and synthesizing some B vitamins (*id.* at ¶¶ 9-10).
- [3] Examples 1-3 of Cavaliere Vesely describe the preparation of an energy drink, an antioxidant beverage, and a multivitamin drink, respectively, containing a mixture of probiotic bacteria and carotenoids (*id.* at ¶¶ 64-71).
- [4] In multivitamin drink Example 3, 0.1 g of a mixture of probiotic lactic acid bacteria is added to 500 ml of a mineral water matrix of water

- 70% orange juice 15%, carrot juice 5%, lemon juice 4%, vitamins (C, niacin, provitamin A, E, pantothenic acid, B6, B2, folacin, biotin, and B12 at an overall concentration of 75 mg/500 ml), sugars 5.85%, and flavors 0.15% (*id.* at ¶¶ 69-71).
- [5] According to Cavaliere Vesely, bacterial cultures containing high concentrations of bacteria in the "thousand million CFU/g", i.e., 10^9 cfu/g, are preferred (*id.* at ¶ 33).
- B. Runge
- [6] Runge discloses powdered concentrates of lactic acid bacterial cultures, preferably comprising about 5×10^8 to 1×10^{12} cfu/g, for preparing foodstuffs and feedstuffs (Runge 1: 4-7; 4:19-28; 6:19-43; claim 18).
- [7] Example S2 teaches preparing a powdered bacterial concentrate containing water, maltodextrin, lactose, NaCl, citric acid, ascorbic acid, K5 bacterial ferment, 5% β carotene, and 2% α -tocopherol (*id.* at 16:8-41).
- C. Berggren
- [8] Berggren discloses a sports drink containing viable lactobacilli, e.g., *Lactobacillus johnsonii* Lji, mixed with micronutrients, including carotenoids and B vitamins, carbohydrates, salts, and proteins, designed to increase energy and fluid levels and to relieve stress (Berggren p. 2, ¶ 5, to p. 3, ¶ 2; p. 4, ¶ 1; p. 6, ¶ 7).
- [9] Example 1 discloses a sports drink prepared from whey proteins, sugars, micronutrients, including β -carotene, fruit juice concentrate, water, and oatbase containing *Lactobacillus* in an amount of $1-2 \times 10^9$ cfu/ml (*id.* at p. 10, ¶ 3, to p. 11, ¶ 4).

- [10] Example 3 discloses a tablet containing *Lactobacillus*, inulin, and micronutrients which can be taken together with about 1/2 liter fluid (*id.* at 12, ¶ 2).

D. Brassart

- [11] Brassart teaches that *Lactobacillus johnsonii* CNCM I-1225 is a lactic acid bacterium with a capacity for immunomodulation and/or reduction of fecal enzymatic activity and that the bacterium may be administered in an ingestible carrier, such as yogurt or a milk-based powder formulation, in a concentration of 10^8 to 10^{10} cfu/g for liquid or frozen forms (Brassart 1:36-59).

E. Reddy

- [12] Reddy teaches mixing lyophilized probiotic lactic acid bacteria, reducing compounds, vitamins, minerals, lecithin, milk derived nutrients, autolyzed yeast extract, and apple fiber into a nutritional supplement tablet (Reddy (1:11-16; 2:11-13, 35-39; 3:9-35)).
- [13] According to Reddy, the yeast extract stimulates bacterial growth in the gastrointestinal tract, provides a B vitamin supplement, supplies most of the major and minor trace minerals (*id.* at 2:52-57), and has "a pronounced effect on the growth of *L. acidophilus* in the presence of bile salts" (*id.* at 7:62-64).

F. The rebuttal Affidavit

- [14] Coinventor Isabelle Bureau-Franz, PharmD, PhD, testified that
- the admixture of a photoprotecting effective amount of at least one probiotic lactic acid bacterium, at least one carotenoid, and a yeast extract elicits an enhanced synergistic effect or response with respect to the photoprotection of the skin. The composition has been found to be

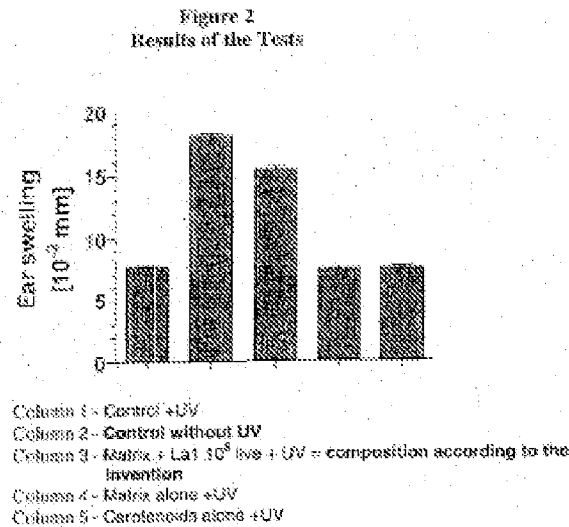
effective ... for preventing inflammation or irritation of the skin after exposure to ultraviolet radiation, ... [and] to provide complete prophylactic protection against the immunosuppressive effects of ultraviolet radiation.

(Affidavit ¶¶ 1, 2, 6).

- [15] Dr. Bureau-Franz identified attached Exhibit B ("Exh. B") as a summary of a contact hypersensitivity ("CHS") reaction test study demonstrating the efficacy of the claimed composition with respect to photoprotection of the skin (*id.* at ¶ 7).
- [16] In the study, mice were divided into four groups -- a control group with no UV exposure, a control group exposed to UV, a sensitized group exposed to the contact allergen 2,4-dinitrofluorobenzene ("DNFB") with no UV exposure, and a sensitized group exposed to DNFB and to UV (*id.*).
- [17] Each of four groups were fed (a) food without additional supplements, (b) food with maltodextrin, (c) food with "matrix," i.e., β -carotene, lycopene, inactivated yeast extract, magnesium stearate, corn starch, and silicon dioxide, (d) food with carotenoids, i.e., matrix without the yeast extract, and (e) food with matrix plus 10^8 cfu/d La1 (Affidavit ¶ 8; Exh. B, Table I).
- [18] "It has been independently determined by the Examiner that 'La1', is, in fact, *Lactobacillus johnsonii* CNCM I-1225" (Ans. 8).
- [19] Dr. Bureau-Franz testified that sensitization occurred about 5 or 6 days after UV exposure by painting either DNFB or acetone on the abdomen of the mouse, followed by a challenge on day 12 after UV

exposure by painting DNFB on right ear of the mouse and acetone on the left ear of the mouse (Affidavit ¶ 9).

- [20] Dr. Bureau-Franz testified that Exhibit B, Figure 2, demonstrates the results of the challenge, expressed as the difference in swelling between the right and left ears (*id.*). Figure 2 is reproduced below.



{Figure 2 of Affidavit Exhibit B demonstrates the results of the DNFB challenge.}

- [21] According to Dr. Bureau-Franz, comparing column 3 (invention) to column 2 (control without UV exposure) shows "the skin reacted readily to the presence of the allergen on the right ear because the animal did not experience local immunosuppression due to the exposure to UVR" (*id.* at ¶ 10).
- [22] Further according to Dr. Bureau-Franz, "the formulas corresponding with the data of columns 1 and 4-5 proved unsuccessful in preventing local immunosuppression resulting from UVR exposure" (*id.* at ¶ 11).

III. Discussion

A. Legal principles

"[T]he test [for obviousness] is what the combined teachings of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425 (CCPA 1981). A rejection under 35 U.S.C. § 103(a) is based on the following factual determinations: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any objective indicia of non-obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 399 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)).

In *KSR*, the Court also reaffirmed that evidence of unexpected results may rebut an examiner's prima facie case of obviousness. 550 U.S. at 416. However, to establish that claimed subject matter yields an unexpected result, the claimed subject matter must be compared to the closest prior art. *In re Baxter Travenol Labs.*, 952 F.2d 388, 392 (Fed. Cir. 1991) ("[W]hen unexpected results are used as evidence of nonobviousness, the results must be shown to be unexpected compared with the closest prior art."). Moreover, "objective evidence of nonobviousness must be commensurate in scope with the claims." *In re Kulling*, 897 F.2d 1147, 1149 (Fed. Cir. 1990) (quoting *In re Lindner*, 457 F.2d 506, 508 (CCPA 1972)); see also *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003) ("[A]pplicant's showing of unexpected results must be commensurate in scope with the claimed range.").

B. Analysis

Claim 1 broadly recites an orally administrable composition containing a photoprotecting effective amount of at least one probiotic lactic acid bacterium, from 10^{-12} to 20 % by weight of at least one carotenoid, a

yeast extract, and an orally acceptable carrier. Cavaliere Vesely discloses orally administrable compositions, i.e., non-milk beverages, containing at least one probiotic lactic acid bacterium and at least one carotenoid in an orally acceptable carrier (FF 1-4). Appellants do not dispute the Examiner's finding that the bacterium and the carotenoid are present in the claimed amounts (Ans. 4) (also compare FF 4-5 and Spec. 5:11-15 (the probiotic lactic acid bacteria is present in an amount of at least 10^5 cfu/g carrier)). Reddy discloses mixing probiotic bacteria with yeast extract (FF 12) and teaches that the yeast extract stimulates bacterial growth, provides a B vitamin supplement, and supplies most of the major and minor trace minerals (FF 13). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to add a yeast extract to the probiotic bacteria-containing beverages of Cavaliere Vesely to stimulate bacterial growth and supply B vitamin and trace minerals as taught by Reddy.

Runge and Berggren likewise disclose orally administrable compositions containing at least one probiotic lactic acid bacterium and at least one carotenoid in an orally acceptable carrier in undisputedly the claimed amounts (FF 6-10). Therefore, it would have been likewise *prima facie* obvious to one of ordinary skill in the art to add a yeast extract to the probiotic bacteria-containing compositions of Runge and Berggren to stimulate bacterial growth and supply B vitamin and trace minerals as taught by Reddy.

To overcome a *prima facie* case of obviousness, a showing of unexpected results must be based on a comparison with the closest prior art. *Baxter Travenol Labs.*, 952 F.2d at 392. Here, the closest prior art, the compositions of Cavaliere Vesely, Runge, or Berggren, contain both at least

one probiotic bacterium and at least one carotenoid in an orally acceptable carrier (FF 4-9). Thus, Appellants' comparison to compositions that do not contain at least one probiotic bacterium and at least one carotenoid, is not a comparison to the closest prior art which teaches combining at least one probiotic bacterium with at least one carotenoid.

Second, a showing of unexpected results must be commensurate in scope with the claimed subject matter. *Kulling*, 897 F.2d at 1149. Here, the single composition shown by Appellants, food with matrix plus 10^8 cfu/d *Lactobacillus johnsonii* CNCM I-1225 (FF 17-18), is not commensurate in scope with the claimed subject matter. There are multiple genera of probiotic lactic acid bacteria (see e.g., claim 2), each of which contain a number of species (see e.g., claim 3). Furthermore, there may be multiple strains of each bacterial species (see e.g., claim 4). Appellants' showing is limited to a single strain of a single species of a single genus of probiotic lactic acid bacteria, i.e., *Lactobacillus johnsonii* CNCM I-1225. Appellants' showing also uses two carotenoids, β -carotene and lycopene, whereas the claimed subject matter recites "at least one carotenoid." In addition, but for the amount of probiotic bacteria in the food, the showing does not state the amounts of the other food components, e.g., β -carotene or lycopene. Similarly, while the claimed subject matter broadly recites "a photoprotecting effective amount" of at least one probiotic lactic acid bacterium, the showing is limited to a single concentration of bacterium. Therefore, Appellants' showing is not commensurate in scope with the claimed subject matter.

Third, Appellants contend that the claimed subject matter "elicits an enhanced synergistic effect or response with respect to the photoprotection

of the skin" (FF 14) based upon their showing of a lack of local immunosuppression in mice fed food with matrix plus 10^8 cfu/d *Lactobacillus johnsonii* CNCM I-1225. However, Brassart explicitly teaches that *Lactobacillus johnsonii* CNCM I-1225 has a capacity for immunomodulation (FF 11). Thus, it may well be that the lack of local immunosuppression shown in mice fed food with matrix plus 10^8 cfu/d *Lactobacillus johnsonii* CNCM I-1225 is a function of the specific strain of *Lactobacillus johnsonii* used. Therefore, Appellants' showing fails to establish even a synergistic effect or response with respect to the photoprotection of the skin.

C. Conclusion

We will sustain the rejection of claims 1-10 and 25-30 under 35 U.S.C. § 103(a) over Cavaliere Vesely, Runge, Berggren, Brassart, and Reddy. The evidence of record supports a *prima facie* conclusion that it would have been obvious to modify the compositions of Cavaliere Vesely, Runge, and Berggren by adding a yeast extract thereto; and, Appellants have not provided evidence that, when weighed with the evidence of obviousness, is sufficient to overcome the *prima facie* conclusion of obviousness.

IV. Order

Upon consideration of the record, and for the reasons given, it is

ORDERED that the decision of the Examiner to reject claims 1-10 and 25-30 as unpatentable under 35 U.S.C. § 103(a) over the combined teachings of Cavaliere Vesely, Runge, Berggren, Brassart, and Reddy is AFFIRMED; and,

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FURTHER ORDERED that no time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(vi).

AFFIRMED

cdc

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